

Doetinchem, June 25, 2021

Dear customer,

With this letter I would like to inform you about a **possible** safety issue with products which we recently delivered to you.

Products concerned:

50129-30-OEM Collimator OPT30, CF002, ARCOMA, RAL9003

With the following serial numbers:

WOE027081/1-1, WOE026165/1-1, WOE027076/1-1, WOE027077/1-1, WOE027080/1-1, WOE027029/1-1, WOE027337/1-1, WOE027074/1-1.

Description of the problem:

It has been identified that the product markings of the collimator laser do not comply with the test certificate. Therefore, it can't be confirmed that the product delivered is a class II laser product which complies with the test certificate.

Hazard related to the problem:

The risk related to this problem is currently being investigated and worst case it could mean that the laser product is a higher risk class than intended which could result in an eye injury hazard to the patient and/or end user when integrated in a system and put into service.

Action required:

Prevent the concerned products from being put into service until further notice.

Follow up:

We are currently investigating this issue with the highest priority and we would like to keep you informed about the process. Therefore, we suggest to have a call the coming days to explain the situation and to answer any question you might have.

We are very sorry for the inconvenience caused and hope to have informed you sufficiently for the moment.

Yours truly,

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Vice President & General Manager Connect and Control Solutions